

### REMARKS/ARGUMENTS

Applicant wishes to thank the Examiner for the courtesy of conducting a personal interview in the Examiner's office on July 21, 2004. During the course of the interview, Applicant argued that Applicant's invention provides for reducing the normal dosage of a pharmaceutical given to a patient for the treatment of a disorder without reducing its effectiveness by taking advantage of the placebo effect, as distinguished from the references cited by the Examiner in rejecting Applicant's claims, namely, U.S. Patent No. 5,760,095 issued to White and U.S. Patent No. 6,255,325 issued to Dariani *et al.* In Applicant's invention, the placebo is administered substantially contemporaneously with an amount of pharmaceutical at least during one predetermined time period.

The White patent relates to a method of gradually weaning a person from caffeine dependency by providing the patient with pills which, over a period of time, have gradual reductions of caffeine and gradual increases of an analgesic. In certain embodiments of White, a placebo may be given following the medicament regimen for psychological advantages. Column 4, Lines 55 and 56. From Column 6, Lines 6-22 of White, it is clear that the placebo is given after caffeine intake has ceased.

In the Dariani patent, the placebo is used in the standard manner of a clinical trial in order to prove the effectiveness of the new drug. In Dariani, the placebo is never given substantially contemporaneously with the drug as set forth in Applicant's independent Claims 1, 19, 30, and 42. Applicant's independent Claim 43 states that the placebo is administered "along with" the drug.

It is therefore submitted that neither the White patent nor the Dariana patent, taken alone or in combination together or with other references cited by the Examiner, do not anticipate or render Applicant's claimed invention obvious.

During the course of the interview, the Examiner indicated that the term "pharmaceutical" in Applicant's claims were too broad. The Examiner suggested that the Applicant amend his claims to the extent that the pharmaceutical is taken from the group consisting essentially of methylphenidate and dextroamphetamine. Applicant agreed to make those suggested changes to the claims. All of the claims have now been amended accordingly. In addition, Applicant has added "salts thereof" to the preamble of each independent claim and to the specification in Paragraph 0030. It is submitted that salts are implied in reference to the specific drug and that no new matter has been added. In addition, one skilled in the art of treating ADHD would recognize a reference to dextroamphetamine in the treatment of ADHD to include salts thereof since salts of dextroamphetamines are often used as the drug for the treatment. The term dextroamphetamine is often used by those skilled in the art as shorthand to include salts thereof.


During the course of the interview, the Examiner also indicated that when allowable subject matter has been found regarding the claims which have been examined in this application, namely, Claims 1-18 and Claims 30-41, the restriction requirement will be withdrawn and the Examiner will extend the search to include the non-elected claims, namely, Claims 19-29 and 42-44.

The Examiner also suggested that normal dosage, which is set forth in the preamble of independent Claims 1, 19, and 30, be defined in the specification. Applicant has amended Paragraph 30 in the specification to define the terms full dosage, normal dosage and usual dosage, which are used interchangeably in the specification, to mean the dosage amount given to a patient which is medically appropriate to treat the patient's condition without regard to the dosage reduction techniques taught by this invention. It is submitted that this amendment to the specification contains no new matter.

In view of the above amendment and remarks, it is believed that this application is in condition for allowance. An early allowance is solicited.


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